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| 10/782,827 | 02/23/2004 | Audrey VanStockum | SNH 3001 | 5450 |

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| EXAMINER | |
|---|---|
| ARNOLD, ERNST V | |
| **ART UNIT** | **PAPER NUMBER** |
| 1616 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/782,827 | VANSTOCKUM, AUDREY | |
| | Examiner | Art Unit | |
| | Ernst V. Arnold | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7,9-17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-7, 9-17 and 19-26 are pending.

During the interview on 05/23/07, it was brought to the Examiner's attention that the artifact filed on 11/20/2006 was overlooked by the Examiner. To correct this oversight, the Examiner is hereby expressly withdrawing finality and sending this non-final Office Action.

The artifact filed on 11/20/2006 contained 'before and after' type color photographs of individuals with various skin pigmentation problems. Such photographs may also be observed at: http://recouleur.com/photo.asp. The artifact provided color evidence for the treatment of vitiligo and skin re-pigmentation.

**Withdrawn rejections:**

Claims 1-7, 9-17 and 19-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (US 6,149,933) in view of Montes (US 4,985,443), Kolyadenko et al. (International Journal of Artificial Organs 2000, 23(8), 568) and Randic et al. (Biology of Reproduction 1973, 8, 495-498). The Examiner is withdrawing this rejection in favor of the rejection below.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 9-17 and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (US 6,149,933) in view of Klett-Loch (US 6,013,279).

Applicant claims a method of treating vitiligo or **grey hair** and methods of restoring pigmentation of skin or **hair** in a human patient in need thereof.

**Determination of the scope and content of the prior art**

**(MPEP 2141.01)**

Nelson teaches methods of suppressing or reversing graying of hair and pigment restoration (Abstract and claims 9 and 21). Nelson teaches copper salts in the amount of about 1.0 to about 10 mg/day (column 3, lines 7-27). Nelson suggests the addition of other B-complex vitamins (Column 3, lines 50-52). Nelson provides guidance on the amount of vitamin B5, greater than 10 mg/day and vitamin B6, greater than 2 mg per day (column 3, lines 28-53). Nelson teaches a daily dose of 125 mg of calcium ascorbate (column 5, examples 1 and 2) as well as ascorbic acid 200 mg per day (column 4, lines 13-20 and column 6, line 8). Nelson teaches a method comprising a

dietary supplement in the form of a tablet for oral administration with 38.4 mg copper per day, pyridoxine HCl of 3 mg per day, zinc in the form of zinc oxide of 15 mg per day, calcium pantothenate of 819 mg per day (Column 4, lines 5-8 and Column 6, example 6). Nelson teaches that the formulations can be formed into other forms that may be more acceptable to the consumer (column 7, lines 30-35).

Thus Nelson fairly teaches and suggests a method of reversing gray hair with a composition comprising copper, vitamin C (ascorbate), zinc, pantothenic acid, hydrochloric acid and B-complex vitamins.

Klett-Loch teaches hair compositions comprising 0.09 wt. % folic acid and 0.001 wt. % vitamin B12 (Claims 1-13).

**Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)**

1. Nelson does not expressly teach adding vitamin B12 (cyanocobalamin) or folic acid (vitamin B9) in their methods. This deficiency in Nelson is cured by the teachings of Klett-Loch.

2. Nelson does not expressly teach subcutaneously administering vitamin B12.

3. Nelson does not expressly teach a method of restoring pigmentation of the skin or hair where the components are compounded into a topically applied formulation.

**Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add vitamin B12 and folic acid to the composition and method of Nelson and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) Nelson suggests adding other B-complex vitamins and 2) B-complex vitamins such as cyanocobalamin and vitamin B9 are common in the art of hair care, as taught by Klett-Loch. It is merely routine optimization of the ingredients taught by Nelson and Klett-Loch by one of ordinary skill in the art to arrive at the instant invention. It is the Examiner's position that if the tablet of Nelson finds its way under the tongue then that is sublingual administration.

With respect to claims 19 and 20, Nelson does not expressly teach a method of restoring pigmentation of skin or hair in the absence of copper on days when the female patient is undergoing menses. However, the interruption of the components administered during the treatment regimen in the method is deemed, in the absence of evidence to the contrary, inconsequential as the expected result of restoring pigmentation to the hair remains the same. The hair is treated. At [0025] of the instant specification, Applicant states that copper levels are elevated during menses and copper supplementation could lead to copper toxicity. However, no data has been shown to support this assertion. Therefore, it is the Examiner's position that the expected result of hair treatment would be obvious to one of ordinary skill in the art.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made subcutaneously administer vitamin B12 to the composition and method of Nelson and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because various routes of administration, including injection subcutaneously, of vitamin B12 are known to one of ordinary skill in the art. The expected result remains the same: the patient receives vitamin B12.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to compound the components of Nelson into a topically applied formula and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Nelson clearly teaches alternative forms can be made for the consumer and topical lotions, creams, soaps, shampoos and gels are known to one of ordinary skill in the art of hair care.

Please note that simply walking outside exposes one to the sun and UV radiation.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Summary:**

The art reasonably teaches a method of re-pigmentation of grey hair with a composition comprising copper, vitamin C (ascorbate), zinc, pantothenic acid, hydrochloric acid and B-complex vitamins.

Applicants artifact filed on 11/06/2006 contained color photographs related to the skin condition vitiligo. While providing evidence for the treatment of skin pigmentation/vitiligo, the artifact is not commensurate in scope with the claimed subject matter. The re-pigmentation of the skin in the treatment of vitiligo is not the same as the treatment of grey hair.

***Conclusion***

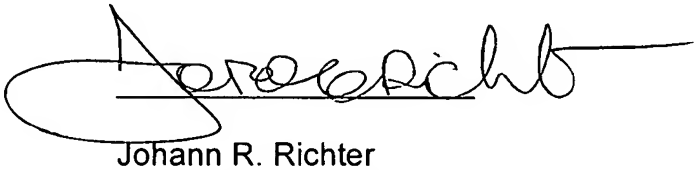
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616



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